

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

) MDL No. 1456
) Master File No. 1:01-CV-12257-PBS
) Sub-Category Case No. 1:08-CV-11200
)

THIS DOCUMENT RELATES TO:
*United States ex rel. Linnette Sun and Greg
Hamilton, Relators*
v.
Baxter Healthcare Corporation

) Judge Patti B. Saris
)

) **LEAVE TO FILE GRANTED ON**
) **03/12/2012**
)

**BAXTER HEALTHCARE CORPORATION'S RESPONSE TO
STATEMENT OF THE UNITED STATES IN RESPONSE TO
THE ELECTRONIC ORDER OF FEBRUARY 24, 2012**

A. Introduction

On February 24, 2012, the Court asked the government to state whether “it seeks to take a position on the statutory claim that the relators [in the *Sun/Hamilton* case, Civil Action No. 1:08-11200-PBS], had a statutory right to notice of settlement of its claims and a right to be heard [in the *Ven-A-Care* case, Civil Action No. 1:06-11337-PBS].”¹ The government’s March 3, 2012 response, *Sun/Hamilton* Docket No. (“Doc. No.”) 166 (“Gov. Resp.”), answers the Court’s question “no,” by asserting on the last page of its pleading that “Sun and Hamilton never had the right or obligation to request a hearing under Section 3730(c)(2)(B) on the proposed settlement between Ven-A-Care and Baxter”

We agree that the Sun/Hamilton relators had no statutory right to notice or to a hearing in the *Ven-A-Care* case. Neither Sun nor Hamilton was a party to *Ven-A-Care*, although both relators are in privity with the government in this action. We nevertheless

¹ Both the *Sun/Hamilton* and the *Ven-A-Care* case are under the Master AWP docket 1:01-cv-12257-PBS.

hasten to point out that Sun and Hamilton (1) had actual notice of the *Ven-A-Care* settlement and (2) took no action in connection with that settlement before the Court dismissed that case. Even if Sun and Hamilton had timely complained of the *Ven-A-Care* settlement, however, the government's power to consent to the settlement in that case would still have been unassailable.

In a variation of its earlier rejected argument that the *Ven-A-Care* Settlement Agreement and Release does not cover Advate or Recombinate claims (despite explicit language to the contrary), the government now asserts that it somehow lacked authority or power to settle claims in a non-intervened False Claims Act ("FCA") case. Gov. Resp. at 4-5. As demonstrated below, this assertion cannot be reconciled with federal court decisions or the government's own articulation of its unrestricted power to settle FCA claims.

There is a final order and judgment in *Ven-A-Care*, consented to by the government. That final order and judgment forecloses certain claims elsewhere by or on behalf of the government, including the Advate and Recombinate claims in this case, although – we agree – not the entire case itself.

B. Background

On January 26, 2012, after full briefing, the Court ruled that the Sun/Hamilton relators' claims regarding Advate and Recombinate are precluded by the final judgment in *Ven-A-Care* – a dismissal with prejudice in accordance with the terms of the Settlement Agreement and Release to which the government consented. January 26, 2012 Memorandum and Order, Doc. No. 158 ("Mem. and Order")². Unhappy with this

² Baxter also moved for summary judgment on the Recombinate and Advate claims on a variety of other bases. The Court found it unnecessary to address the alternate grounds. The Court, of course, could grant summary judgment to Baxter on these separate grounds

outcome, the Sun/Hamilton relators have now tried a wholly new argument, asserting that their claims are not precluded because they were allegedly entitled to notice of the filing of the Settlement Agreement and Release. Doc. No. 159. We demonstrated in opposition that relators were not entitled to the extraordinary remedy of reconsideration because there was no manifest error of law or newly discovered evidence. Doc. No. 161; *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 82 (1st Cir. 2008). We also pointed out – without denial by Sun or Hamilton – that relators received actual notice of the filing of the Settlement Agreement and Release in any event.

This actual notice would doom relators’ new argument even if there were no other grounds to reject it, but there are. First, as explained below, the statutory notice requirement does not apply because it covers only the dismissal of “actions,” not “claims.” Second, the real party in interest had notice in any event of the *Ven-A-Care* dismissal proceedings (and indeed participated in them), and since the government cannot pursue claims it settled against Baxter, its representatives cannot either. Third, the government’s contention that it was powerless to enter into an agreement dismissing claims without intervening is wrong as a matter of law.

C. The Final Judgment in *Ven-A-Care* Would Preclude the Assertion of Advate and Recombinate Claims in this Case on Behalf of the Government Even If Relators Had Not Received Actual Notice of the Settlement Agreement and Release

Even if the Sun/Hamilton relators had not received notice of the *Ven-A-Care* Settlement Agreement and Release, their position would be untenable. That settlement and dismissal did not entitle Sun and Hamilton to notice and a hearing in *Ven-A-Care*.

and moot any dispute regarding the preclusive effect of the Settlement Agreement and Release.

**1. The FCA Notice Provision Governs the Dismissal of
“Actions,” Not Claims**

The FCA requires notice and a hearing only when the government dismisses or settles a relator’s “action”—not a “claim” that the relator may be asserting on the government’s behalf. § 3730(c)(2)(A) and (B). There is thus no statutory requirement for notice and a hearing to nonparties when the government dismisses or settles one FCA action and that dismissal or settlement might have an effect on the claims in *another* FCA action. Indeed, it might be impossible for a defendant to provide notice to unidentified relators in sealed cases, yet under relators’ view here such a defendant would be settling at its peril – that is, always vulnerable to the possibility that the bargained-for release could be attacked on procedural grounds. This Court properly recognized that one relator’s settlement may bar a second relator’s claims. Mem. and Order at 7-8. In any event, because the government in *Ven-A-Care* did not settle or dismiss the Sun/Hamilton *action*, the FCA notice and hearing provisions on which the Sun/Hamilton relators rely simply do not apply.

**2. Moreover, the Government Is the Real Party in Interest
Here and Unquestionably Participated in the *Ven-A-Care* Dismissal**

The real party in interest in this case is the government, not Sun or Hamilton. *See United Seniors Ass’n v. Philip Morris USA*, 500 F.3d 19, 24 (1st Cir. 2007) (government remains the “real party in interest” in a *qui tam* case); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004) (same).³ As the Court has correctly held, any FCA claims regarding Advate and Recombinate are

³ Because the underlying claim belongs to the government and not the *qui tam* relators, “the Government must consent to all dismissals in a *qui tam* action brought by a private person, even voluntary dismissal by the plaintiff-relator.” *U.S. ex rel. Globe Composite Solutions, LTD. v. Solar Construction Inc.*, 528 F.Supp. 2d 1, 3 (D. Mass. 2007).

foreclosed by the plain language of the Settlement Agreement and Release in *Ven-A-Care*. The government has already been paid under that settlement. Relators' newly conceived "notice" argument is nothing more than an impermissible collateral attack on a final judgment. But "[a] judgment that is entered with prejudice under the terms of a settlement, whether by stipulated dismissal, a consent judgment, or a confession of judgment, is not subject to collateral attack by a party or a person in privity, and it bars a second suit on the same claim or cause of action." *Langton v. Hogan*, 71 F.3d 930, 935 (1st Cir. 1995). *See also Baella-Silva v. Hulsey*, 454 F.3d 5, 9-11 (1st Cir. 2006) (settlement agreement incorporated into final judgment cannot be collaterally attacked on the basis of legal errors). It is well-settled that in all FCA cases a final judgment binds not only the government, regardless of whether it participates in the case, but also any other relators who stand in the shoes of the government. *See United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009).

D. The Government Had the Power and Authority to Settle or Dismiss the FCA Claims of Sun/Hamilton Even Without Intervening in Their Case

The government argues that its involvement in a *qui tam* case is limited to "three paths" and, because it took none of those paths in this case, it could not have settled claims in the *Sun/Hamilton* action. Gov. Resp. at 2-3. This argument is incorrect and directly contrary to the position the Justice Department is currently taking before the U.S. Court of Appeals for the District of Columbia.

In *United States ex rel. Schweizer v. Oce N.V.*, 681 F. Supp. 2d 64 (D.D.C. 2010), *argued*, No. 11-7030 (1st Cir. Jan. 13, 2012), Schweizer filed a *qui tam* complaint alleging that Oce and related entities had violated the FCA by knowingly selling non-complying products to the government in violation of the Trade Agreements Act. Later,

Schweizer and Vee filed an amended complaint, adding Vee as a plaintiff. The government declined to intervene in the suit. Even though it had not intervened, the government, the relators, and Oce entered into settlement negotiations. Vee and the government reached a settlement agreement with Oce; Schweizer did not agree to settlement terms. On the basis of the settlement, the government then moved to dismiss the action with respect to its claims and those of Vee. The government also moved to dismiss the claims of Schweizer.

The district court ruled that the government has an unfettered right to dismiss a *qui tam* suit. The court, relying upon *Hoyte v. American Nat'l Red Cross*, 518 F.3d 61, 65 (D.C. Cir. 2008), and *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003), explained:

This is because the statute itself refers to the government's ability to dismiss the action (without mention of requiring leave of court), *Swift*, 318 F.3d at 252, as well as the government's nearly absolute discretion under the Take Care Clause to bring suit in its name, *id.* at 253 (quoting *Heckler v. Chaney*, 470 U.S. 821, 831, 105 S. Ct. 1649, 84 L. Ed. 2d 714 (1985)). Indeed, in a similar context the Court of Appeals noted that "[f]ew subjects are less adapted to judicial review than the exercise by the Executive of his discretion in deciding when and whether to institute criminal proceedings, or what precise charge shall be brought or whether to dismiss a proceeding once brought." *Newman v. United States*, 382 F.2d 479, 480, 127 U.S. App. D.C. 263 (D.C. Cir. 1967) (Burger, J.). Likewise [] the Court of Appeals' decision in *Hoyte* places the government's decision to dismiss a *qui tam* action beyond judicial review. 518 F.3d at 65.

Schweizer, 681 F. Supp. 2d at 66.

On appeal, Schweizer argues, *inter alia*, that neither *Hoyte* nor *Swift* apply because neither involved a settlement. In response, the government argues that "it has an unfettered right to dismiss a *qui tam* suit," see Declaration of Shamir Patel in Support of Baxter Healthcare Corporation's Response to Statement of the United States in Response

to the Electronic Order of February 24, 2012 (“Patel Decl.”) Ex. A (Br. for Appellee United States at 14) (“Gov. Br.”), “intervention is not necessary for the Government to dismiss a qui tam case,” *id.* at 19 (citing *Swift v. United States*, 318 F.3d at 251-52), and, more fundamentally, when – as in *Ven-A-Care* – the court approves a settlement as part of the judgment in the case,

the settlement would not simply be an agreement enforceable through contract law remedies. Rather, the settlement could also be enforceable, when necessary, through the means for enforcing judgments. *See Kokkonen v. Guardian Life Insurance Co. of America*, 511 U.S. 375, 380-81 (1994).

Patel Decl., Ex. A (Gov. Br. at 29).

We believe that the government, consistent with the *Hoyte* and *Swift* decisions and its recent arguments to the D.C. Circuit in *Schweizer*, could have dismissed Sun and Hamilton’s FCA claims without first taking over or intervening in the *Sun/Hamilton* case. This Court need not reach the issue, however, or address the government’s power or authority under the FCA or the Constitution’s Take Care Clause. The Court has already ruled that the *Ven-A-Care* final judgment resolved all *claims* regarding Recombinate and Advate.

E. Conclusion

Sun and Hamilton were not entitled to notice of the *Ven-A-Care* dismissal, even though they in fact received actual notice and did not timely file any motion with the Court prior to that dismissal. Even if this were not so, however, and there had been legal errors in the entry of the final judgment in *Ven-A-Care* – and there were not – any such alleged legal errors would have been insufficient under controlling First Circuit authority to sustain a collateral attack against a judgment consented to in writing by the government, the party whose claims the relators here purport to assert.

DATED this 23rd day of MARCH 2012.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, caused a true and correct copy of the foregoing, Baxter Healthcare Corporation's Response to Statement of the United States in Response to the Electronic Order of February 24, 2012, to be delivered to all counsel of record by electronic service via ECF and LexisNexis File & Serve, on March 23, 2012 for posting and notification to all parties.

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